

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202971Orig1s000

OTHER ACTION LETTERS



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202971

COMPLETE RESPONSE

Otsuka Pharmaceutical Company, Ltd.
c/o Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: David Goldberger, R.Ph., RAC
Senior Director, Regulatory Affairs
2440 Research Blvd.
Rockville, MD 20850

Dear Mr. Goldberger:

Please refer to your New Drug Application (NDA) dated September 26, 2011, received September 26, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ABILIFY MAINTENA (aripiprazole) extended-release injectable suspension for intramuscular (IM) injection 300 mg/vial and 400 mg/vial.

We acknowledge receipt of your amendments dated October 13, 2011, October 14, 2011, October 26, 2011, November 7, 2011, November 9, 2011, December 20, 2011, December 21, 2011 (2), December 23, 2011, January 9, 2012, January 23, 2012, January 26, 2012, January 27, 2012, February 23, 2012, March 22, 2012, March 26, 2012, March 28, 2012, March 30, 2012, April 13, 2012, April 25, 2012, May 10, 2012, May 14, 2012, May 22, 2012, May 24, 2012, May 25, 2012, June 13, 2012, June 21, 2012, June 27, 2012, June 29, 2012 (2), July 3, 2012, July 5, 2012, July 17, 2012, July 18, 2012, and July 25, 2012.

We have completed our review of this application and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

FACILITY INSPECTIONS

During a recent inspection of the (b) (4) manufacturing facility our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

LABELING

Please submit labeling identical to attached as agreed upon on July 18, 2012.

Your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels identical to attached as agreed upon on July 25, 2012.

OTHER

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants," May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Carton and Container Labeling

60 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
07/26/2012